

JAN - 6 2012

5. 510(k) Summary

In accordance with the requirements of the Safe Medical Device Act, Touch Medical Solutions Inc. herewith submits a 510(K) summary for the following device.

Submitter Name/Address: Touch Medical Solutions, Inc.
3455 University Parkway
Winston-Salem NC 27106-4109

Contact Person/Tel. #: James Owen
(336) 413-6967

Date Summary Prepared: December 2, 2010

Establishment No:

Trade/Proprietary Name: TouchPACS Suite

Common/Usual Name: Medical Imaging Workstation

Classification Name: Picture Archiving and Communications System

Class/Panel: Class II, 90-LLZ, 21CFR 892.2050

Predicate Devices:

Manufacturer	Device	510(k)
STAIR Systems Inc.	Stair Systems PACS & DICOM Viewer	K100236
Ramsoft Inc.	Ramsoft PACS	K031562
Advance Imaging Solutions, LLC	EZPACS	K062878
Fuji Medical System USA	Fuji Synapse Workstation Software	K051553

INTENDED USE STATEMENT

The TouchPACS Suite software system is a picture archiving and communications system (PACS) intended to be used as a networked Digital Imaging and Communications in Medicine (DICOM) and non- DICOM information and data management system. The TouchPACS Suite PACS & DICOM Viewer Software is comprised of modular software programs that run on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems. TouchPACS TouchMGR Suite DICOM Viewer Software system is an image, data storage and display software that accepts DICOM data from any OEM modality which support DICOM standard imaging data. The system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulation, create graphical representations of anatomical areas, and perform quantitative measurements.

The TouchPACS Suite software is not for mammographic use.

DEVICE DESCRIPTION

The TMS TouchPACS Suite is a collection of software applications coded in the Microsoft C# application language, using the Windows Presentation Foundation (WPF) libraries for user interface, that run on "off-the-shelf" Microsoft Windows-based personal or business computers to provide diagnostic imaging workstation capabilities. The system is designed to provide an environment for radiological diagnosticians which is "easy on the eyes"; so that the user can use the system for 10-12 hours per day without undue strain.

Note: the TouchPACS Suite imaging software uses the MyDICOM .NET C# Source Code Libraries, from myDICOM LLC, compiled directly into the imaging applications, to provide full DICOM v3 compliance.

The layout and design of the 3-screen user interface evolved from the legacy concept of 3 separate computers, each with a single monitor displaying a single element of the case under review, into a modern, multi-monitor native design which incorporates large performance gains through the use of Microsoft's DirectX imaging technologies.

The core of the system is the database, which is a relational design, using Microsoft SQL Server 2008 Enterprise edition as the Relational Database Management System (RDBMS). The database server provides a dedicated, central place to provide disaster recovery servicing (via standard SQL Server replication), as well as the large multi-terabyte storage required for a PACS system.

Attached to the RDBMS are TouchPACS client workstations, TouchMGR client workstations, and servers required for system operations: TMS DICOM SCP Server and Microsoft SQL Server. All of the aforementioned software modules, except for Microsoft SQL Server, are TMS software products.

The TouchPACS Suite PACS client workstation is intended to be a desktop computer replacement product, with the interface dominating the screen space on a workstation computer. This design decision was made to accommodate non-technical doctors who, we found, typically prefer to have a simplified and unobtrusive environment to work in. Color-based exam status listings were evolutionary, growing from the legacy 'field of green' display listing into the more advanced dynamic, multicolored tree view seen today in the client. TouchPACS is a multi-monitor capable client, currently configurable in a 1, 2, or 3 monitor footprint.

The TouchMGR client workstation represents the nerve center of the TouchPACS Suite, providing services for securing the TMS network, maintaining users, allowing paperless workflow, and other such critical day-to-day system maintenance tasks. TouchMGR users will include hospital or practice administrators, security administrators, and functional personnel who may need to make modifications to data contained in the TMS database. TMS uses DSN-less connections to the database, usually requiring port 1433 to be set as an exception in the workstation's firewall rule set. The client performs many

tasks, some of which are not relevant to every customer, though we encourage adoption of TMS electronic processes by our clients in order to help them streamline their office efficiency. Users only see the functions of the Touch MGR modules which they are entitled to view or use, based on security settings captured at login time. The The TMS DICOM SCP Server provides multi-threaded DICOM v3 server capabilities of the TouchPACS system. It was built to be run unattended, but a user interface, available from either the desktop or the TouchMGR client, may be used to both help monitor and control the various DICOM storage processes necessary to import each radiological study from an external source (modality, another PACS, etc.). The server incorporates a DICOM SCP service grouping that allows for DICOM ping response, client protocol negotiation, transfer syntax negotiation, and several other system-level DICOM negotiations. As each case is received, it is stored via a Service host to the local hard drive, then it is queued for storage, and then is stored as data to the main database in one of 8 available simultaneous, threaded "put away" processes.

PREDICATE DEVICE COMPARISON

Product Name	TouchPACS	STAIR Systems Constellation PACS	RamSoft PACS	Fuji Synapse Workstation Software	EZPACS
510(k) Number		K100236	K031562	K051553	K062878
Communications	TCP/IP	TCP/IP	TCP/IP	TCP/IP	TCP/IP
Image Archive	Yes	Yes	Yes	Yes	Yes
Image Processing	Yes	Yes	Yes	Yes	Yes
Image Edit	Yes	Yes	Yes	Yes	Yes
Edit Patient Demographics	Yes	Yes	Yes	Yes	Yes
Add and remove images	Yes	Yes	Yes	Yes	Yes
Combine studies	Yes	Yes	Yes	Yes	Yes
Edit Patient Orientation information	Yes	Yes	Yes	Yes	Yes
Set and Edit Routing Information	Yes	Yes	Yes	Yes	Yes
JPEG Lossy/Lossless Compression	Display = Yes Apply = LOSSLESS	Yes	Yes	Yes	Yes
JPEG 2000 Lossy/Lossless Compression	Display = Yes Apply = LOSSLESS	Yes	Yes	Yes	Yes
Image	Yes	Yes	Yes	Yes	Yes

Processing (image scaling)					
Image Processing (Window Level, Pan, Zoom, Cine Display)	Yes	Yes	Yes	Yes	Yes
DICOM Print	Yes	Yes	Yes	Yes	Yes

The TMS TouchPACS Suite has similar intended use and technical features of the predicate devices listed above. The TouchPACS Suite is not for mammographic use.

SAFETY INFORMATION

The TouchPACS Workstation software introduces no new safety and efficacy issues other than those already identified with the predicate devices. The results of a hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the May 29, 1998 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The Instructions for Use contains precautions and warnings for safe and effective use of the device.

Potential hazards are identified through risk analysis and managed through the software development process and verification/validation testing.

The TouchPACS Workstation Software complies with the following mandatory and voluntary standards:

- ACR/NEMA DICOM Version 3.0 (Digital Imaging and Communications in Medicine) - developed by the American College of Radiology and the National Electrical Manufacturers Association. The Synapse DICOM Conformance Statement has been included in the Labeling section as Appendix F3.
- ***Note: the TouchPACS Suite imaging software uses the MyDICOM .NET C# Source Code Libraries, from myDICOM LLC, compiled directly into the imaging applications, to provide full DICOM v3 compliance.***

Recommended Specifications for Workstation Hardware include compliance with the following standards:

- General Safety standards for all hardware: IEC60950 or equivalent.
- Information Technology Equipment, Radio Disturbance (Emissions) Characteristics-Limits and Methods of Measurements, IEC/CISPR 22 (EN55022)

CONCLUSIONS

A comparison of the labeling, substantial equivalence table, and verification and validation testing has established that the device meets its intended use and design specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. James Owen
Director of Development
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3455 University Parkway
WINSTON-SALEM NC 27106-4109

JAN - 6 2012

Re: K112008
Trade/Device Name: TouchPACS Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 6, 2011
Received: December 14, 2011

Dear Mr. Owen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

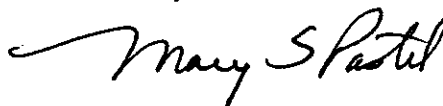
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Mary S. Pastel". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use**510(k) Number (if known):** K112008**Device Name:** TouchPACS Suite**Indications for Use:**

The TouchPACS Suite software system is a picture archiving and communications system (PACS) intended to be used as a networked Digital Imaging and Communications in Medicine (DICOM) and non- DICOM information and data management system. The TouchPACS Suite PACS & DICOM Viewer Software is comprised of modular software programs that run on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems. TouchPACS TouchMGR Suite DICOM Viewer Software system is an image, data storage and display software that accepts DICOM data from any OEM modality which support DICOM standard imaging data. The system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulation, create graphical representations of anatomical areas, and perform quantitative measurements.

The TouchPACS Suite software is not for mammographic use.

Prescription Use X
(Part 21CFRS801Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Mary S. Pestil
(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112008